



23 April 2004

Commander
U.S. Army Medical Materiel Agency
(ATTN: MAJ Patrick Garman)
1423 Sultan Drive, Suite 100
Fort Detrick, MD 21702-5001

Dear MAJ Garman:

HemCon, Inc. is pleased to announce that the company has established the stability of the HemCon® Bandage for up to 12 months from the date of manufacture and the ability of the Army to continue using these products beyond the currently labeled 6 month expiration date. Testing conducted by the company demonstrates that bandages are stable for 12 months after the original date of manufacture. Bandages will be labeled with an expiration date of 12 months for all future lots.

Medical device regulations prohibit HemCon from relabeling product once out of our direct control. In the case of the HemCon® Bandages, this includes any products shipped from our facility. However, to assist you with determining the appropriateness of continuing to use bandages previously distributed with 6 months shelf life, a table of all such lot numbers and original expiration dates is attached. Ending alpha characters on lot numbers represent different packaging operations and will not affect expiration date. For example, lot "M30204001" would include M30204001H, M30204001I, M30204001J, *etc.* The one exception to this convention is Lot M3042201 (shown in ***bold italics*** print in the table). All individual expiration dates for each of M3042201's sublots are listed in the table.

The extension is to a total of 12 months from date of manufacture, or 6 months beyond the current expiration date. This is not the addition of another 12 months. Any HemCon® Bandages with lot numbers not on this list either have 12 months shelf life already printed on the label and should not be extended, or have already exceeded a 12 months shelf life.

Please do not hesitate to contact me if there is any other assistance we can provide for your notification process. Thank you for using the HemCon® Bandage.

Best regards,

Kevin Hawkins
Quality Manager

HemCon® Bandage Lots Distributed with Six Months Shelf-Life:

| Lot | 6 Month Expiration Date |
|--------------------------|--------------------------------|
| M30331002 | 31-October-03 |
| M30421001 | 29-February-04 |
| <i>M30422001</i> | 30-November-03 |
| <i>M30422001H</i> | 30-November-03 |
| <i>M30422001I</i> | 31-December-03 |
| <i>M30422001J</i> | 31-December-03 |
| <i>M30422001K</i> | 30-November-03 |
| <i>M30422001L</i> | 30-November-03 |
| M30505001 | 31-December-03 |
| M30512001 | 31-January-04 |
| M30513001 | 31-January-04 |
| M30520001 | 31-December-04 |
| M30527001 | 29-February-04 |
| M30616001 | 29-February-04 |
| M30623001 | 31-January-04 |
| M30707001 | 29-February-04 |
| M30721001 | 31-January-04 |
| M30722001 | 29-February-04 |
| M30728001 | 31-January-04 |
| M30811001 | 29-February-04 |
| M30818001 | 31-March-04 |
| M30819001 | 31-March-04 |
| M30827001 | 31-March-04 |

| Lot | 6 Month Expiration Date |
|------------|--------------------------------|
| M31021001 | 31-May-04 |
| M31027001 | 31-May-04 |
| M31103001 | 31-May-04 |
| M31112001 | 31-May-04 |
| M31119001 | 31-May-04 |
| M31124001 | 31-May-04 |
| M31210001 | 30-June-04 |
| M31215001 | 30-June-04 |
| M31217001 | 30-June-04 |
| M31229001 | 31-July-04 |
| M40105001 | 31-July-04 |
| M40112001 | 31-July-04 |
| M40114001 | 31-July-04 |
| M40119001 | 31-July-04 |
| M40128001 | 31-August-04 |
| M40129001 | 31-August-04 |
| M40202001 | 31-August-04 |
| M40204001 | 31-August-04 |
| M40210001 | 31-August-04 |
| M40212001 | 31-August-04 |
| M40301001 | 30-September-04 |
| M40303001 | 30-September-04 |
| M40308001 | 30-September-04 |

Note: All lot numbers not in *italics* include any sub lot numbers designated by an additional alpha character on the labeled lot number.